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Computerized Tailored Interventions for Behavioral Sequelae of Post-Traumatic Stress Disorder in Veterans

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14. ABSTRACT

This project assesses the usability and feasibility of a multi-behavioral computerized tailored intervention (CTI) or expert system delivered via the Internet for veterans with Post-Traumatic Stress symptoms. Three behavioral health risk factors, (1) smoking, (2) depression, and (3) stress, that are associated with PTSD, will be included in the CTI system. The project will adapt and modify a CTI system based on the Transtheoretical Model of Behavior Change (TTM) that has been successfully utilized with general adult populations to be relevant to a veteran population. The study will utilize methods that are characteristic of a product development project. Each of the four project phases are sequential and will build upon the results of the previous phase. Phase 1 focuses on the review of current CTI programs on smoking cessation, stress management, and depression prevention, and integrating them into a multi-behavioral program for application with veterans. Phase 2 will include the development and adaptation of text-based feedback messages and multimedia components for smoking cessation, stress management, and depression prevention. Initial testing of the modified CTI programs will commence in Phase 3. Cognitive and usability testing with veterans will be performed, and additional modifications to the behavioral modules will be made based on the test results. Phase 4 will focus on feasibility testing of the multi-behavioral CTI system with veterans.

15. SUBJECT TERMS: none provided

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INTRODUCTION

The overall aim of this project is to enhance the emotional and physical well-being of veterans with Post-Traumatic Stress symptoms through the reduction of smoking, depression, and stress with the use of an empirically based computerized tailored intervention (CTI) or expert systems. The more immediate objective of the project is to adapt and modify a successful CTI system for the general adult population to be relevant and applicable to military veterans with Post-Traumatic Stress symptoms, particularly those who have been deployed to Iraq and Afghanistan. Research with returning Operation Iraqi Freedom (OIF) and Operation Enduring Freedom (OEF) veterans suggests that there is a new generation of veterans with high levels of Post-traumatic Stress Disorder (PTSD) and depression (Hoge et al., 2006). Therefore, it is critical that we identify effective ways to increase access to efficacious treatments for combat-related PTSD and associated co-morbid behavioral health conditions. Further, due to the rapid development of telemental health programs throughout the military, it is crucial that research address the effectiveness of this mode of service delivery for specialty services such as PTSD treatment.

This proof of concept project will develop and pilot test a viable Internet-based intervention to assist veterans with Post-Traumatic Stress symptoms to progress toward changing negative health behaviors that are associated with PTSD and are often difficult to change. Most commercially available CTIs and software applications have limited impact, because of the lack of theory-driven material and empiricism. The proposed CTI is supported by more than 30 years of scientific evidence, and uses the Transtheoretical Model of Behavior Change (TTM) as the theoretical basis for generating personalized interventions (Prochaska & Velicer, 1997; Velicer, Prochaska, & Redding, 2006). The TTM is ideally suited to those who are resistant to change and unlikely to take action in the near future, as well as those prone to relapse.

The intervention will be primarily targeted at negative coping strategies that confound or exacerbate Post-Traumatic Stress symptoms and hinder progress toward remission. Progress in a TTM conceptual framework may be defined as movement from one TTM stage of change to the next level of the change process, rather than the elimination or significant reduction of smoking, depression, or stress per se. The CTI system that will be modified during this project has been empirically tested and validated with a general population and has demonstrated significant outcomes for the three proposed modules — smoking cessation, depression prevention, and stress management. The proposed CTI system will provide an intervention that emphasizes advancement through the processes of change at one's own pace as the focus of project, rather than the linear progression through a structured behavior change program to achieve changes in the undesired behaviors.

Hypothesis 1: *The structure and TTM-based content of the adapted Smoking Cessation, Depression Prevention, and Stress Management systems and consequent CTI will be appropriate for veterans.*

> **Primary Aim 1:** To modify TTM-based Smoking Cessation, Depression Prevention, and Stress Management behavioral intervention modules, originally developed for general adult populations, to be appropriate and relevant for veterans with Post-Traumatic Stress symptoms.

Secondary Aim 1a: To conceptualize the CTI program's approach, content, and design based on input from a diverse sample of military veterans and expert consultants.

Hypothesis 2: *A multi-behavioral CTI can be successfully implemented with veterans who have Post-Traumatic Stress symptoms*

Primary Aim 2: To demonstrate that a multi-behavioral CTI can be successfully implemented with veterans with Post-Traumatic Stress symptoms.

Secondary Aim 2a: To conduct usability interviews with veterans to ensure that the target population can navigate through the computerized intervention and understand the intervention content.

Secondary Aim 2b: To demonstrate the feasibility of CTI by: a) recruiting veterans to the project and delivery of the proposed intervention; and b) assessing the acceptability and perceived usefulness of the intervention from the perspective of veterans with Post-Traumatic Stress symptoms.

Secondary Aim 2c: To demonstrate feasibility of CTI to increase motivation to change targeted behaviors, i.e., smoking cessation, depression prevention, and stress management.

Secondary Aim 2d: To demonstrate positive change in assessment outcomes for Post-Traumatic Stress symptoms, depression, quality of life, and perceived stress.

BODY

During the first year of the project, several delays and personnel changes impacted the anticipated progress. A summary timeline is presented below.

1. The project was awarded 12-August-2009.
2. Revised protocol was reviewed and approved by the VA IRB at their November 19, 2009.
3. UH IRB approval notification was received on January 19, 2010.
4. Protocol packet was prepared for second level review, and submitted to MRMC ORP Human Research Protections Office (HRPO) through TATRC on February 9, 2010.
5. Transition of PI from Dr. Sarah Miyahira to Dr. James L. Spira, Ph.D. approved by funding agency on July 27, 2010.
6. Human Use approvals received from HRPO for both UH and VA protocols on March 8, 2010.
7. Budget Reallocation request approved on Sept. 17, 2010.
8. Research Project Manager offered position in late August to start in end of September 2010.
9. Plan to request a no-cost extension in order to complete project.

Task 1: IRB Protocol review and approval – 100% Complete

1a. Local IRB
1b. 2nd level-USAMRMC

Task 2: Project planning and coordination – in progress (ongoing; 20% complete)

Task 3: Focus groups for 3 modules - in planning stage (5% complete)

3a. Recruit veterans
3b. Conduct focus groups
3c. Analyze data & identify content changes

Task 4: Integrate modules into multi-behavioral CTI with single home page (1% complete)

Task 5: Modify & tailor 3 modules to veterans (1% complete)

5a. Modify content of feedback narratives for each module
5b. Modify CTI program

Task 6: Conduct beta test & usability interviews (0% complete)

6a. Beta test CTI system
6b. Recruit veterans & conduct usability interviews
6c. Modify CTI program

Task 7: Conduct feasibility study (0% complete)

7a. Recruit veterans & orient to CTI system
7b. Conduct monthly and post assessments
7c. Analyze data & interpret results

Task 8: Submit final report (0% complete)

8a. Prepare & submit final report
8b. Initiate manuscript preparation
8c. Prepare presentation for scientific meeting

KEY RESEARCH ACCOMPLISHMENTS

1. Human use approvals by both local IRB and ORP/HRPO.
2. Approved modifications to change PI (from Miyahira to Spira)
3. Approved budget reallocation.
4. Research Project Manager hired.

REPORTABLE OUTCOMES

1. All protocol elements (e.g., study design, informed consent, recruitment materials, etc.) have been approved by the local VA and USAMRMC (ORP).

2. Research Project Manager has been hired.

CONCLUSION

Protocol revisions were approved by the local IRB and ORP human use in August. Necessary budget modifications were approved and the timeline has been extended one year to make up for time spent on protocol revisions. The project continues to progress. The PI change (from Dr. Miyahira to Dr. Spira) is being finalized. A research Project Manager is being hired, and a revised timeline has been created (see attached). Working with staff at PHREI, the Pro-Change subaward will be processed before the end of October, 2010. Drs. Jim Prochaska (originator of the TTM) and Kerry Evers (Pro-Change) will meet with the team October 21-22 to review the approved protocol and establish roles and responsibilities of all members of the team. A plan to recruit individuals for the study is currently being prepared, in cooperation with Dr. Julia Whealin at the National Center for PTSD in Honolulu.

Given the delays in start-up, it is likely that a no-cost extension will be requested prior to the end of the POP. To date, very few funds have been spent on the project, so funding will not be an issue.

REFERENCES

1. Hoge, C. W., Auchterlonie, J. L., & Milliken, C. S. (2006). Mental health problems, use of mental health services, and attrition from military service after returning from deployment to Iraq or Afghanistan. Journal of the American Medical Association, 295(9), 1023-1032.

2. Prochaska, J. O., & Velicer, W. F. (1997). The transtheoretical model of health behavior change. American Journal of Health Promotion, 12, 38-48.

3. Velicer, W. F., Prochaska, J. O., & Redding, C. A. (2006). Tailored communications for smoking cessation: past successes and future directions. Drug & Alcohol Review, 25, 49-57.

APPENDIX (Revised Timeline)

	Task Name	Duration	Start	Finish
1	Project Duration	655 days?	Mon 8/10/09	Fri 2/10/12
2	**Reports**	**I04 days?**	**Fri 11/5/10**	**Wed 5/23/12**
13	**IRB protocols (site 1 & 2)**	**53 days**	**Wed 7/1/09**	**Fri 9/11/09**
17	Project planning & coordination of multi-team sites	45 days	Wed 10/20/10	Tue 12/21/10
18	**Conduct focus groups (site 2)**	**128 days**	**Wed 10/20/10**	**Fri 4/15/11**
19	Recruit Veterans (n=30)	23 days	Wed 10/27/10	Fri 11/26/10
20	Conduct focus groups	23 days	Mon 11/29/10	Wed 12/29/10
21	Analyze data & identify content modifications	15 days	Thu 12/30/10	Wed 1/19/11
22	**Integrate 3 Modules into single muli-behavioral CTI homepage**	**128 days**	**Wed 10/20/10**	**Fri 4/15/11**
23	Testing and system integration	60 days	Mon 1/24/11	Fri 4/15/11
24	**Modify modules (language, tone, & content-all sites)**	**68 days**	**Wed 10/20/10**	**Fri 1/21/11**
28	**Conduct CTI system beta & usability testing (site 3)**	**51 days**	**Mon 4/18/11**	**Mon 6/27/11**
29	Recruit Veterans (n=15)	23 days	Mon 4/18/11	Wed 5/18/11
30	Conduct system beta testing	21 days	Mon 4/18/11	Mon 5/16/11
31	conduct usability interviews with veterans (n=15)	15 days	Tue 5/17/11	Mon 6/6/11
32	Modify system based on interview data as needed	15 days	Tue 6/7/11	Mon 6/27/11
33	**Conduct feasibility study (site 1)**	**100 days**	**Thu 5/19/11**	**Wed 10/5/11**
34	Recruit participants and orient to CTI system (n=50)	40 days	Thu 5/19/11	Wed 7/13/11
35	Conduct 1 month online assessment	20 days	Thu 7/14/11	Wed 8/10/11
36	Conduct 3 month post assessment	40 days	Thu 8/11/11	Wed 10/5/11
37	Analyze & interpret data (site 1&3)	30 days	Thu 10/6/11	Wed 11/16/11
38	**Submit final report**	**90 days**	**Thu 11/17/11**	**Wed 3/21/12**